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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/569,814	02/28/2006	Takashi Ueno	UENO 12	6639

1444 7590 12/10/2008

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
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WASHINGTON, DC 20001-5303

EXAMINER	
HIBBERT, CATHERINE S	

ART UNIT	PAPER NUMBER
1636	

MAIL DATE	DELIVERY MODE
12/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/569,814	UENO ET AL.	
	Examiner	Art Unit	
	Catherine S. Hibbert	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *1-6,8,9 and 11-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/30/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the First Action on the Merits of US Application 10/569,814, filed 28 February 2006, which is a National Stage entry of PCT/JP04/012172, filed 25 August 2004, which claims Foreign Priority to JP Application 2003-307624, filed 29 August 2003. Claims 1-16 are pending. Claims 1-6, 8-9 and 11-16 are withdrawn to non-elected subject matter. Claims 7 and 10 are under examination in this action.

Election/Restrictions

Applicant's election with traverse of Group III (Claims 7 and 10) and of the species:

-"a nucleotide sequence that encodes a protein or a part of the protein" (as claim 1 (1));

-"the non-translatable nucleotide sequence is located downstream of the protein-encoding nucleotide sequence linked to the promoter sequence in a translatable state" (as claim 2);

-"cell" as the type of system between "cell" versus "cell-free"; and

-"a nucleotide sequence that encodes a protein in a target gene" (e.g. claim 7),

in the reply filed on 30 June 2008 is acknowledged.

The traversal is on the ground(s) that Applicants state that "the prior art relied upon to allegedly destroy unity of invention does not do so, and that the generic nature of the invention which extends through all the claims forms a single general inventive concept under PCT Rule 13.1 because of the same or corresponding special technical feature or features in those claims, in accordance with PCT Rule 13.2." Applicants

additionally state that "even if the broader generic concept were not patentable, and such is not admitted, there would still be a narrower single general inventive concept throughout the claims under PCT Rules 13.1 and 13.2.". In addition, Applicants traverse the requirement for election of species stating that

> Applicants do not deny that the species may indeed be patentably distinct from one another. However, it cannot at this stage be properly said that the election of species is properly based on lack of unity of invention under PCT Rules 13.1 and 13.2, because the generic claims clearly establish that the species are linked to form a single general inventive concept under PCT Rules 13.1 and 13.2 as called for in the generic claims.

This argument is respectfully not found persuasive for reasons of record and below. Unity of invention is lacking because the common technical feature that unites the Groups is a nucleic acid construct of Claim 1, having a promoter sequence, at least one protein-encoding nucleotide sequence linked to the promoter sequence in a translatable state, and a poly A signal sequence, wherein the nucleic acid construct further contains, between the promoter sequence and the poly A signal sequence, a nontranslatable nucleotide sequence that is different from the protein-encoding nucleotide sequence, (the protein-encoding nucleotide sequence linked to the promoter sequence in a translatable state and the nontranslatable nucleotide sequence that is different from the protein-encoding nucleotide sequence being linked together so that they are transcribed from the nucleic acid construct in a single RNA molecule), and the nontranslatable nucleotide sequence consisting of either (1) a nucleotide sequence that encodes a protein or a part of the protein; or (2) a nucleotide sequence of an untranslated region that is naturally located on the 5' or 3' side of a nucleotide sequence

that encodes a protein. However, this feature is not considered a special technical feature because the feature is not novel over the prior art as the feature is anticipated by Yokota et al. in "Inhibition of intracellular hepatitis C virus replication by synthetic and vector- derived small interfering RNAs" (EMBO reports Vol. 4, No. 6, 2003) or Pachuk, C.J. in "Methods and Constructs for Evaluation of RNAi Targets and Effector Molecules" (WO2004/076629), cited in search report) (see especially page 603, Figure 1 legend).

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-6, 8-9 and 11-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 30 June 2008.

Priority

It is noted that Applicant cannot rely upon the foreign priority papers to overcome a prior art rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 30 May 2006 has been considered by the examiner with the exception of the Foreign Patent Document WO 2002/04509A2, for which no copy has been provided. It is acknowledged that Applicant provided the US 2004/0106565A1 citation as an English language equivalent of the WO 2002/04509A2 and the examiner has considered this US Patent document.

Specification

The disclosure is objected to because of the following informalities: The sentence beginning: "Furthermore, plural functional nucleotide molecules" (page 34, lines 3-6) contains a typographical error in the omission of a verb linking the term "library" and "be used". Appropriate correction is required.

Claim Objections

Claims 7 and 10 are objected to because of the following informalities: Claims 7 and 10 are dependent from the withdrawn claims 1 and 5.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 (and therefore dependent Claim 10) is indefinite because the phrase "a nucleotide sequence that encodes a protein in a target gene", in lines 7-8 (step 1), is indefinite because it is unclear whether the "nucleotide sequence" is "in a target gene" or whether the "protein" is in a target gene, and it is further unclear how a protein could be in a target gene. Therefore one of ordinary skill in the art would not be able to determine what is encompassed by the phrase "a nucleotide sequence that encodes a protein in a target gene".

Additionally, Claim 10 is indefinite because it is unclear whether the "method" of line 1 is "according to Claim 7" or whether the intention of the Claim is that only "the functional nucleotide molecule" is according to Claim 7. Therefore, one of ordinary skill in the art would not be able to determine the metes and bounds of what is encompassed by Claim 10.

Claim interpretation

Claims 7 and 10 are directed to a method of detecting an activity of altering expression of a target gene by a functional nucleotide molecule, the method comprising the steps of: (1) transcribing an RNA from the nucleic acid construct defined by claim 1 or the vector defined by claim 5 which has, as a nontranslatable nucleotide sequence, a nucleotide sequence that encodes a protein in a target gene; (2) contacting (in a cell/Claim 10) a nucleotide molecule with the RNA transcribed in step (1); (3) detecting the RNA in step (2) or a translation product translated from the RNA; and (4) detecting an activity of altering expression of the target gene by a functional nucleotide molecule based on the amount of the RNA or the translation product translated from the RNA detected in step (3).

Claims 1 and 5 define the constructs of Claims 7 and 10 and as such are directed to a nucleic acid construct (or vector containing the construct/claim 5) having a promoter sequence, at least one protein-encoding nucleotide sequence linked to the promoter sequence in a translatable state, and a poly A signal sequence, *wherein* (1) the nucleic acid construct further contains, *between* the promoter sequence and the poly A signal sequence, a nontranslatable nucleotide sequence *that is different from* the

protein-encoding nucleotide sequence, (2) the protein-encoding nucleotide sequence linked to the promoter sequence in a translatable state and the nontranslatable nucleotide sequence that is different from the protein-encoding nucleotide sequence are linked together so that they are transcribed from the nucleic acid construct in a single RNA molecule, *and* (3) the nontranslatable nucleotide sequence is a nucleotide sequence that encodes a protein or a part of the protein.

It is noted that for examination purposes claims must be given their broadest reasonable interpretation in light of the specification as would be understood by one of ordinary skill in the art.

Therefore, it is noted that the term "different" used in lines 7 and 11 to distinguish the translatable and nontranslatable nucleotide sequence components of the nucleic acid construct of Claim 1 can be read broadly as either non-overlapping or not identical. Therefore, the sequences could be read as overlapping in the same protein encoding region but with a nontranslatable extension which would be considered a different sequence. These two sequences would then be considered "linked" and would be "transcribed from the nucleic acid construct in a single RNA molecule".

In addition, it is noted that the phrase in step (1) of Claim 7, "transcribing **an** RNA from the nucleic acid construct defined by claim 1", encompasses any short sequence of RNA that is encoded by the claimed nucleic acid construct but does not require any particular segment of that claimed nucleic acid construct for the expressed RNA.

In addition, it is noted that the instant specification defines "a functional nucleotide molecule" on page 14, lines 13-15 as follows: "As used herein, a functional

nucleotide molecule refers to a nucleotide that alters expression of a protein." In addition, regarding the term "a nontranslatable nucleotide sequence", the instant specification states: "a nontranslatable nucleotide sequence means that a nucleotide sequence is in a form designed theoretically not to be translated or translated at a negligible trace level, in other words, that a nucleotide sequence is not translated substantially".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Doench et al in "siRNAs can function as miRNAs" (Genes & Development, Vol. 17; pages 438-442, February 15, 2003; of record in the IDS).

Doench et al teach a method of detecting an activity of altering expression of target genes using siRNAs as functional nucleotide molecules (see page 439, Figure 1 and legend), the method comprising the steps of: (1) transcribing an RNA from the nucleic acid construct defined by claim 1 (e.g. p. 441, Materials and methods: paragraph headed DNA constructs and siRNAs) which has, as a nontranslatable nucleotide sequence, a nucleotide sequence that encodes a protein in a target gene; (2) contacting (in Hela cells, p. 439, Figure 1 and legend) a nucleotide molecule with the RNA transcribed in step (1); (3) detecting the RNA in step (2) or a translation product

translated from the RNA; and (4) detecting an activity of altering expression of the target gene by a functional nucleotide molecule based on the amount of the RNA or the translation product translated from the RNA detected in step (3) (e.g. see page 439, RNA and protein analysis, Figure 1 and legend, panels C and E).

Therefore, Doench et al meets the limitations of Claims 7 and 10.

Claims 7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Yokota et al in "Inhibition of intracellular hepatitis C virus replication by synthetic and vector-derived small interfering RNAs" (EMBP, Vol. 4; pages 602-608, January 2003; of record in the IDS). Claim interpretation is as described above.

Yokota et al teach a method of detecting an activity of altering expression of Hepatitis C virus target genes using siRNAs as functional nucleotide molecules (see abstract), the method comprising the steps of: (1) transcribing an RNA from the nucleic acid construct defined by claim 1 (e.g. p. 603, Figure 1 and legend) which has, as a nontranslatable nucleotide sequence, a nucleotide sequence that encodes a protein in a target gene; (2) contacting (in Huh7 and 293T cells, p. 607) a nucleotide molecule with the RNA transcribed in step (1); (3) detecting the RNA in step (2) or a translation product translated from the RNA; and (4) detecting an activity of altering expression of the target gene by a functional nucleotide molecule based on the amount of the RNA or the translation product translated from the RNA detected in step (3) (e.g. see Northern and Western blotting analysis page 605, Figure 4 and legend).

Therefore, Yokota et al meets the limitations of Claims 7 and 10.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Hibbert whose telephone number is (571)270-3053. The examiner can normally be reached on M-F 8AM-5PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully submitted,
Catherine S. Hibbert
Examiner/AU1636

/David Guzo/
Primary Examiner
Art Unit 1636